4160-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 524

[Docket No. FDA-2011-N-0003]

Ophthalmic and Topical Dosage Form New Animal Drugs; Eprinomectin

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule; technical amendment.

SUMMARY: The Food and Drug Administration (FDA) is amending the animal drug regulations to reflect approval of a supplemental new animal drug application (NADA) filed by Merial Ltd. The supplemental NADA provides for addition of a warning statement against the use of eprinomectin topical solution in preruminating calves intended for veal.

DATES: This rule is effective [INSERT DATE OF PUBLICATION IN THE FEDERAL REGISTER].

FOR FURTHER INFORMATION CONTACT:

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SUPPLEMENTARY INFORMATION: Merial Ltd., 3239 Satellite Blvd., Bldg. 500, Duluth, GA 30096-4640 filed a supplement to NADA 141-079 for EPRINEX (eprinomectin) Pour-On for Beef and Dairy Cattle, a topical solution used for the treatment and control of internal and external parasites of cattle on pasture with persistent effectiveness. The supplemental NADA provides for addition of a warning statement against the use of eprinomectin topical solution in preruminating calves intended for veal. The NADA is approved as of September 23, 2011, and the regulations are amended in 21 CFR part 524 to reflect the approval.

Approval of this supplemental NADA did not require review of additional safety or effectiveness data or information. Therefore, a freedom of information summary is not required.

The Agency has determined under 21 CFR 25.33 that this action is of a type that does not individually or cumulatively have a significant effect on the human environment. Therefore, neither an environmental assessment nor environmental impact statement is required.

This rule does not meet the definition of "rule" in 5 U.S.C. 804(3)(A) because it is a rule of "particular applicability." Therefore, it is not subject to the congressional review requirements in 5 U.S.C. 801-808.

List of Subjects in 21 CFR Part 524

Animal drugs.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs and redelegated to the Center for Veterinary Medicine, 21 CFR part 524 is amended as follows:

PART 524--OPHTHALMIC AND TOPICAL DOSAGE FORM NEW ANIMAL DRUGS

1. The authority citation for 21 CFR part 524 continues to read as follows:

Authority: 21 U.S.C. 360b.

2. Revise § 524.814 to read as follows:

§ 524.814 Eprinomectin.

(a) Specifications. Each milliliter (mL) contains 5 milligrams (mg) of eprinomectin.

(b) Sponsor. See No. 050604 in § 510.600(c) of this chapter.

(c) Related tolerances. See § 556.227 of this chapter.

(d) Special considerations. See § 500.25 of this chapter.

(e) Conditions of use in cattle--(1) Amount. Apply 5 mg (1 mL) per 10 kilograms (kg) of body weight (500 micrograms/kg) applied topically along backbone from withers to tailhead.

(2) Indications for use. For treatment and control of gastrointestinal roundworms (Haemonchus placei (adult and L4), Ostertagia ostertagi (adult and L4, including inhibited L4), Trichostrongylus axei (adult and L4), T. colubriformis (adult and L4), T. longispicularis (adult), Cooperia oncophora (adult and L4), C. punctata (adult and L4), C. surnabada (adult and L4), Nematodirus helvetianus (adult and L4), Bunostomum phlebotomum (adult and L4), Oesophagostomum radiatum (adult and L4), Strongyloides papillosus (adults), Trichuris spp. (adults)); lungworms (Dictyocaulus viviparus, adult and L4); cattle grubs (all parasitic stages Hypoderma lineatum, H. bovis); lice (Damalinia bovis, Linognathus vituli, Haematopinus eurysternus, Solenopotes capillatus); mange mites (Chorioptes bovis, Sarcoptes scabiei); and horn flies (Haematobia irritans). Controls and protects from reinfection of D. viviparus for 21 days after treatment and H. irritans for 7 days after treatment.

(3) Limitations. A withdrawal period has not been established for preruminating calves. Do not use in calves to be processed for veal.

Dated: November 18, 2011.

Steven D. Vaughn,

Director, Office of New Animal Drug Evaluation,

Center for Veterinary Medicine.

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